

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, February 24, 2026
Time: 9:00 am US Arizona Time
Location: Zoom Teleconference
Institution: Banner Research, Gilbert, AZ
Principal Investigator: Matthew Ulrickson, MD
Protocol: A2 Biotherapeutics, Inc., A2B395-101
NCT Number: NCT06682793
Meeting Type: Continuing Review of Protocol and Site
Title: DENALI-1: A Seamless Phase 1/2 Study to Evaluate the Safety and Efficacy of A2B395, an Allogeneic Logic-gated Tmod™ CAR T, in Heterozygous HLA-A*02 Adults with Recurrent Unresectable, Locally Advanced, or Metastatic Solid Tumors That Express EGFR and Have Lost HLA-A*02 Expression.

1. Call to order:

The Meeting was called to order at 9:12 am US Arizona Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Four voting members were present, including one local member unaffiliated with the institution. Also present were five Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair noted changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for A2B395, since it consists of allogeneic T cells modified by a lentiviral vector.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of A2B395 locally**, provided all other criteria for study closure are met.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. The Committee noted that the study agent will be prepared in syringes which are then brought to the dosing room and recommended that Biosafety SOP Addendum Section 3.3.1 be revised to add details about internal transportation of prepared dosing syringes.
2. An Institutional Representative confirmed that the biohazardous waste containers in the dosing rooms are not labeled with a biohazard symbol. During dosing, a container lined with a red biohazardous waste bag is brought into the room and after dosing is immediately removed from the container, and brought to the full biohazardous waste storage area and placed into a biohazard-labeled container.
3. The Committee acknowledged that study staff have brought this to the attention of Banner administration and that study staff has no control over Banner policy in these areas.
4. The Committee suggested that Banner Research revise policies to comply with Arizona State Code. Specifically, Arizona Administrative Code R18-13-1407 states that biohazardous medical waste placed inside a red bag shall be placed in a secondary container. This container shall be constructed of materials that will prevent breakage of the bag in storage and handling during collection and transportation and bear the universal biohazard symbol. Alternatively, the code states that biohazardous medical waste may be placed in a reusable container that bears the universal biohazard symbol.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:18 am US Arizona Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 1.0, dated 11-01-2025

Investigator's Brochure, Edition 2.0, dated 07-16-2025

Investigational Product Manual, Version 3.0, dated 03-19-2025

Research Modification Evaluation, Investigator's Brochure, Edition 2.0

Research Modification Evaluation, Investigational Product Manual, Version 3.0

Biological Risk Assessment and Summary, updated 08-11-2025

Site Map, BMDACC Infusion Suite, dated 05-12-2025

Site Map, BGMC 2nd Floor, dated 08-28-2023

Site Map, BMDACC 3rd Floor, dated 01-23-2026

Site Map, BGMC 5th Floor, dated 08-15-2023

Site Inspection Checklist, T Cell Studies, expires 01-19-2028, updated 02-11-2026

Photos, T Cell Studies, BMDACC and BGMC Dosing Rooms, dated 07-30-2025

Photos, T Cell Studies, BMDACC, Cell Therapy Lab, dated 05-02-2025

Photos, T Cell and Non-T Cell, BMDACC Infusion Area, dated 08-28-2024

Biohazard Sign, Genetically Modified Human Cells, dated 01-13-2026

Biological Safety Cabinet Certifications, Cell Therapy Lab, expire 06-2026

SOP, Biosafety for Genetically Modified Human Cells, dated 06-12-2025

SOP Addendum, Biosafety for Allogeneic Cells, dated 02-11-2026

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

Training, Shipping Certification, expires 06-2027

CRRF, dated 12-02-2025

Prior Meeting Minutes, Initial, dated 03-07-2025

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, February 24, 2026
Time: 9:00 am US Arizona Time
Location: Zoom Teleconference
Institution: Banner Research, Gilbert, AZ
Principal Investigator: Matthew Ulrickson, MD
Protocol: Juno Therapeutics, Inc., 017004
NCT Number: NCT03331198
Meeting Type: Continuing Review of Protocol and Site
Title: An Open-Label, Phase 1/2 Study of JCAR017 in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (017004)

1. Call to order:

The Meeting was called to order at 9:00 am US Arizona Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Four voting members were present, including one local member unaffiliated with the institution. Also present were five Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair noted changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for JCAR017, since it consists of primary human cells modified using a recombinant lentiviral vector. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of JCAR017 locally**, provided all other criteria for study closure are met. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. An Institutional Representative confirmed that the biohazardous waste containers in the dosing rooms are not labeled with a biohazard symbol. During dosing, a container lined with a red biohazardous waste bag is brought into the room and after dosing is immediately removed from the container, and brought to the full biohazardous waste storage area and placed into a biohazard-labeled container.
2. The Committee acknowledged that study staff have brought this to the attention of Banner administration and that study staff has no control over Banner policy in these areas.
3. The Committee suggested that Banner Research revise policies to comply with Arizona State Code. Specifically, Arizona Administrative Code R18-13-1407 states that biohazardous medical waste placed inside a red bag shall be placed in a secondary container. This container shall be constructed of materials that will prevent breakage of the bag in storage and handling during collection and transportation and bear the universal biohazard symbol. Alternatively, the code states that biohazardous medical waste may be placed in a reusable container that bears the universal biohazard symbol.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:11 am US Arizona Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Amendment 6, dated 04-15-2024

Investigator's Brochure, Version 13, dated 02-04-2026

Global Product Administration Manual, Version 1.0, dated 10-31-2025

Research Modification Evaluation, Global Product Administration Manual, Version 1.0

Research Modification Evaluation, Investigator's Brochure, Version 13

Biological Risk Assessment and Summary, updated 02-17-2026

Research Modification Evaluation, PI Change, 06-12-2025

Site Map, BMDACC Infusion Suite, dated 05-12-2025

Site Map, BGMC 2nd Floor, dated 08-28-2023

Site Map, BMDACC 3rd Floor, dated 01-23-2026

Site Map, BGMC 5th Floor, dated 08-15-2023

Site Inspection Checklist, T Cell Studies, expires 01-19-2028, updated 02-11-2026

Photos, T Cell Studies, BMDACC and BGMC Dosing Rooms, dated 07-30-2025

Photos, T Cell and Non-T Cell, BMDACC Infusion Area, dated 08-28-2024

Photos, T Cell Studies, BMDACC, Cell Therapy Lab, dated 05-02-2025

Biohazard Sign, Genetically Modified Human Cells, dated 01-13-2026

SOP, Biosafety for Genetically Modified Human Cells, dated 06-12-2025

SOP Addendum, Biosafety for Autologous Cells, dated 01-13-2026

Training, Shipping Certification, expires 06-2027

CRRF, dated 12-09-2025

Prior Meeting Minutes, Initial, dated 03-17-2025

CV, Ulrickson, M., dated 03-25-2024

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, February 24, 2026
Time: 9:00 am US Arizona Time
Location: Zoom Teleconference
Institution: Banner Research, Gilbert, AZ
Principal Investigator: Matthew Ulrickson, MD
Protocol: Miltenyi Biomedicine, GmbH, M-2018-344
NCT Number: NCT04792489
Meeting Type: Continuing Review of Protocol and Site
Title: A multi-center single arm Phase II study to evaluate the safety and efficacy of genetically engineered autologous cells expressing anti-CD20 and anti-CD19 specific chimeric antigen receptor in subjects with relapsed and/or refractory diffuse large B cell lymphoma

1. Call to order:

The Meeting was called to order at 9:19 am US Arizona Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Four voting members were present, including one local member unaffiliated with the institution. Also present were five Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair noted changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for MBCART2019.1, since it consists of primary human cells modified with a recombinant lentiviral vector. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's, last dose of MB-CART2019.1 locally**, provided all other biosafety criteria required for study closure are met. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

10. Review of proposed facilities and practices:

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Points of Discussion:

1. An Institutional Representative confirmed that the biohazardous waste containers in the dosing rooms are not labeled with a biohazard symbol. During dosing, a container lined with a red biohazardous waste bag is brought into the room and after dosing is immediately removed from the container, and brought to the full biohazardous waste storage area and placed into a biohazard-labeled container.
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3. The Committee suggested that Banner Research revise policies to comply with Arizona State Code. Specifically, Arizona Administrative Code R18-13-1407 states that biohazardous medical waste placed inside a red bag shall be placed in a secondary container. This container shall be constructed of materials that will prevent breakage of the bag in storage and handling during collection and transportation and bear the universal biohazard symbol. Alternatively, the code states that biohazardous medical waste may be placed in a reusable container that bears the universal biohazard symbol.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:23 am US Arizona Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 8.0, dated 12-05-2025

Investigator's Brochure, Edition 10.0, dated 05-30-2025

Apheresis and Investigational Medicinal Product Manual, Version 7.1, dated 06-09-2025

Research Modification Evaluation, Protocol, Version 8.0

Research Modification Evaluation, Investigator's Brochure, Edition 10.0

Research Modification Evaluation, Apheresis and Investigational Med Product Manual, Version 7.0

Research Modification Evaluation, Apheresis and Investigational Med Prod Manual, Version 7.1

Biological Risk Assessment and Summary, updated 01-23-2026

Site Map, BMDACC Infusion Suite, dated 05-12-2025

Site Map, BGMC 2nd Floor, dated 08-28-2023

Site Map, BMDACC 3rd Floor, dated 01-23-2026

Site Map, BGMC 5th Floor, dated 08-15-2023

Site Inspection Checklist, T Cell Studies, expires 01-19-2028, updated 02-11-2026

Photos, T Cell and Non-T Cell, BMDACC Infusion Area, dated 08-28-2024

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Photos, T Cell Studies, BMDACC, Cell Therapy Lab, dated 05-02-2025

Biohazard Sign, Genetically Modified Human Cells, dated 01-13-2026

SOP, Biosafety for Genetically Modified Human Cells, dated 06-12-2025

SOP Addendum, Biosafety for Autologous Cells, dated 01-13-2026

Training, Shipping Certification, expires 06-2027

CRRF, dated 12-15-2025

Prior Meeting Minutes, Continuing, dated 03-07-2025